Remarks

Applicants thank the Office for entering the Applicants' response to a restriction response, filed before the U.S. Patent and Trademark Office, dated June 16, 2009. Claims 1-20 were pending in this application. Claims 5, 15, 16, 18 and 20 have been withdrawn from consideration for allegedly being drawn to a non-elected invention and claims 1-4, 6-14, 17 and 19 have been rejected. By way of this amendment and response, claims 1, 6, 8, 9, 10, 11, 12 and 19 have been amended to more fully claim the subject invention and claims 7 and 13 have been canceled without prejudice and new claim 21 has been added. The support for the claim amendments can be found in the specification, drawings and the original claims of the application as filed. *No new matter has been added*.

Additionally, the Office appears to be under the impression that trademarks used in the instant application are not appropriately designated. Applicants note, however, that, contrary to the Office's contention, the trademarks used in the instant application, namely, KDF® at page 3, line 7 of the corresponding published PCT patent application WO2005/042037 and DOW CHEMICAL® at page 4, line 27 of the foregoing corresponding published PCT patent application have been designated as such. Since these are live trademarks (see, e.g., printouts from the U.S. Patent and Trademark Office trademark database attached herewith evidencing the same), a designation of ® is appropriate in this instance.

Lastly, the Office has objected to the language on page 7, lines 21-23, with respect to the European patent application EP-A-0818228 as being in the name of the Applicant. Applicants would like to clarify that while under the United States patent laws, inventors are applicants, under the European patent laws, an assignee is deemed the applicant. Accordingly, the "Applicant" as referred to in connection with the foregoing European patent application was meant to be Millipore Corporation. Nonetheless, solely in an effort to ensure that the specification meets all the formalities requirements, the appropriate amendment has been made, thereby to replace the Applicant with the inventors in the foregoing European patent application, *i.e.*, Niermeyer *et al.*, at page 7, line 23 of the instant application.

Claim Objections

Claims 1, 3, 6, 7, 8, 10 and 19 have been objected to for various informalities.

Claim 1 has been amended to insert a comma after the term "module" in line 9 (formally line 6), thereby obviating the objection of claim 1 set forth at page 6 of the Office Action mailed 9/15/09.

Claims 3, 6, 7, 10-12 and 19 have been amended to replace "or" with "and" following the phrase "selected from the group consisting of," thereby obviating the objection with respect to these claims, set forth at page 6 of the Office Action mailed 9/15/09.

Regarding claim 10, the space before the ending period has been deleted, thereby obviating the objection with respect to this claim, set forth at page 6 of the Office Action mailed 9/15/09.

Regarding claim 8, the term "group comprising" has been replaced with "group consisting of," thereby obviating the objection with respect to claim 8, set forth at pages 6 and 7 of the Office Action mailed 9/15/09.

In view of the foregoing claim amendments, Applicants respectfully request reconsideration and withdrawal of the claim objections.

Rejections Under 35 USC § 112, Second Paragraph

Claims 1-4, 6-14, 17 and 19 have been rejected as allegedly being indefinite under 25 USC § 112, second paragraph, on the ground that the claims are "narrative in form and replete with indefinite and functional or operative language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device." See, page 7 of the Office Action mailed 9/15/09. Further, claim 1 has been rejected as allegedly being indefinite for the recitation of the phrases "in particular," "means for removably connecting the purification module to the purification system," and "adapted to form part of a fluid purification system."

Without acquiescing to the validity of this rejection and solely in an effort to expedite prosecution and allowance of the pending claims, claim 1 has been amended to more clearly delineate the correlation between the various components of the claimed

device. Specifically, claim 1 now relates to a disposable pretreatment module, wherein the pretreatment module is adapted to be associated upstream of a purification treatment module in a fluid purification system, wherein the treatment module comprising a means for purifying the fluid by tangential filtration and wherein the pretreatment module comprises: (1) a purification pretreatment means; and (2) a housing in which the purification pretreatment means are housed; wherein there is fluid communication between the purification system and the pretreatment module, and wherein the housing contains from the outset a cleaning agent disposed to come into contact with the fluid caused to circulate inside the housing, to clean at least a portion of the purification system downstream of the pre-treatment module following starting a system cleaning procedure.

Similarly, remaining claims have also been amended, as appropriate, to more clearly delineate the correlation between the various structural components of the claimed device.

Applicants understand that the foregoing amendments should obviate each of the indefiniteness rejections and request reconsideration and withdrawal of the same.

Rejections Under 35 USC § 102

Claims 1-4, 7-11, 14, 17 and 19 have been rejected under 35 USC §102(b) as allegedly being anticipated by U.S. Patent No. 4,780,197 in the name of Schuman (hereinafter referred to as "Schuman") on the grounds that Schuman "teaches a module for purifying a fluid (abstract) which is fully capable of being disposed of and fully capable of being adapted to form part of a fluid purification system, and comprising: a fluid purification means (Fig. 2, ref. 56 and col. 4, line 19), a housing (Fig. 3, ref. 24, including ref. 28 and 94 and col. 3, line 33, 34, and 44 and col. 5, line 48) in which the purification means are housed, and a means (Fig. 2, ref. 30, 32, 34 and 38 and col. 3, lines 45-50 and col. 6, lines 35-56) for removably connecting the purification module to a purification system such that it [sic] fluid communication may be established between the purification system and the purification module, the housing containing from the outset a cleaning agent (Fig. 2, ref. 104 and col. 5, line 61) disposed to be fully capable of coming in contact with a fluid caused to circulate inside the housing."

Applicants respectfully traverse this rejection at least for the following reasons. For a prior art reference to anticipate a claimed invention under 35 U.S.C. §102, the prior are reference must teach *each and every limitation* of the claimed invention. See, *Lewmar Marine v. Barient* 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987). As discussed in detail *infra*, *Schuman* fails to teach or suggest each and every limitation of the claimed invention.

It appears that the Office has failed to appreciate the novel and inventive features of the claimed invention as well as the differences between the claimed invention and devices that were in the prior art, including the one disclosed in *Schuman*.

The claimed invention provides a unique purification system which employs a disposable pretreatment module which is capable, among other things, of distributing a cleaning agent into the purification system. For example, as recited in amended claim 1, the claim is directed to a disposable pretreatment module, wherein the pretreatment module is adapted to be associated upstream of a purification treatment module in a fluid purification system, wherein the treatment module comprising a means for purifying the fluid by tangential filtration, and wherein the pretreatment module comprises: (1) a purification pretreatment means; and (2) a housing in which the purification pretreatment means are housed; wherein there is fluid communication between the purification system and the pretreatment module, and wherein the housing contains from the outset a cleaning agent disposed to come into contact with a fluid caused to circulate inside the housing, to clean at least a portion of the purification system downstream of the pretreatment module following starting a system cleaning procedure.

Accordingly, in the purification system of the claimed invention, a cleaning agent is placed in the housing of the pretreatment disposable module from the outset such that it can come in contact with the fluid flow inside the housing and as a result, clean the purification system which is downstream of the pretreatment module following starting a system cleaning procedure. See, for example, page 5, lines 27-33 of the corresponding International PCT patent application no. PCT/IB2004/003724.

Contrary to the Office's contention, the filter and chemical dispenser assembly disclosed in *Schuman* fails to provide a disposable pretreatment module which is located upstream of a purification treatment module in a purification system and which is capable of distributing a cleaning agent to clean at least a portion of the purification system following starting a system cleaning procedure. Notably, the filter and chemical dispenser assembly described in *Schuman* is distinct from the claimed invention, both structurally as well as functionally. For example, in the device of *Schuman*, a chlorinator assembly is placed inside a filter element, where the chlorinator assembly is intended to *clean the fluid circulating through the assembly*. This is in contrast to the claimed invention, where the cleaning agent is placed at the outset inside the pretreatment disposable module, and the cleaning agent is intended to *clean a portion of the purification system downstream of the pretreatment module following starting a system cleaning procedure*.

Further, Schuman also does not teach or suggest means for purifying a fluid by tangential filtration, as claimed.

Accordingly, because *Schuman* fails to teach or suggest each and every limitation of the claimed invention, it cannot anticipate claim 1 or the remaining claims, which depend either directly or indirectly from claim 1.

In view of the foregoing remarks, reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 USC § 103

Claims 6, 12 and 13 have been rejected under 35 USC §103(a) as being unpatentable in view Schuman. Specifically, with respect to claim 6, the Office has taken the position that "a person of ordinary skill in the art at the time of the invention would have found it obvious to use a microfiltration type of filtration means in the module of Schuman . . ." See page 14 of the Office Action mailed 9/15/09. With respect to claim 12, the Office has taken the position that "skilled artisan would have found it obvious to use an agent comprising bleach in the module of Schuman" Id. Lastly, with respect to claim 13, the Office has taken the position that "it would have been obvious to the skilled artisan to include a controller in the module of Schuman . . ." Id.

Applicants respectfully traverse this rejection for the following reasons.

As an initial matter, Applicants note that each of claims 6, 12 and 13 depend, directly or indirectly, from claim 1. Accordingly, these claims inherently include each and every limitation of claim 1. It appears that the Office has failed to even consider each and every limitation of claim 1 in issuing this rejection with respect to the dependent claims 6, 12 and 13. Additionally, Applicants note that claim 13 has been canceled herein, thereby rendering this rejection moot with respect to that claim. Accordingly, the remarks set forth below are in response to this rejection to the extent it relates to claims 6 and 12.

Applicants respectfully submit that the Office has not made a *prima facie* case of obviousness in this instance by failing to provide a rational basis for rendering obvious any of claims 6, 12 and 13. For example, in a recent case, *KSR International Co. v. Teleflex Inc. et al.* (127 S. Ct. 1727 (2007)), the Supreme Court stated that "[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

Applying the foregoing legal precedent to the instant case, Applicants note that the Office appears to make conclusory statements that claims 6, 12 and 13 are obvious in view of *Schuman* coupled with the knowledge of one of ordinary skill in the art, however, the Office fails to provide a rational basis for arriving at such a conclusion.

For example, as discussed above, the claimed invention, as recited in claim 1, relates at least in part to, a disposable pretreatment module, wherein the pretreatment module is adapted to be associated upstream of a purification treatment module in a fluid purification system, wherein the treatment module comprising a means for purifying the fluid by tangential filtration, and wherein the pretreatment module comprises: (1) a purification pretreatment means; and (2) a housing in which the purification pretreatment means are housed; wherein there is fluid communication between the purification system and the pretreatment module, and wherein the housing contains from the outset a cleaning agent disposed to come into contact with a fluid caused to circulate inside the housing, to clean at least a portion of the purification system downstream of the pretreatment module following starting a system cleaning procedure.

Also, as discussed above, the device discussed in *Schuman* is different from the claimed device, both in structure as well as function. To begin with, not only does *Schuman* fails to teach a

disposable pretreatment purification module, as claimed, but it also fails to teach or suggest means for purifying a fluid by tangential filtration means, as claimed.

Each of claims 6 and 12 relate to particular aspects of the claimed invention. Specifically, claim 6 relates to means for purifying a fluid by tangential filtration and claim 12 relates to types of cleaning agents.

Because Schuman does not even teach or suggest means for purifying a fluid by tangential filtration, one of ordinary skill in the art would have had no motivation to use such means in the device of Schuman. Further, arguendo, even if one of ordinary skill in the art were to use a means for tangential filtration in the device of Schuman, one of ordinary skill in the art could not have arrived at the claimed invention, at least based on the differences elucidated above between the claimed device and that disclosed in Schuman. Specifically, even if the means for purifying a fluid by tangential filtration were included in the device of Schuman, one of ordinary skill in the art would not have arrived at the claimed disposable pretreatment module, which is designed to distribute a cleaning agent into the fluid purification system.

Similarly, while Schuman discusses the use of chlorine as a cleaning agent, the Office has failed to appreciate that the device in Schuman is designed to provide a cleaning agent such that to clean a body of water, whereas in case of the claimed device, the cleaning agent is provided from the outset to clean at least a portion of the purification system. As such, based on the teachings of Schuman along with the knowledge in the art, one of ordinary skill in the art would not have had any motivation to use the cleaning agent disclosed in Schuman the way it is used in the claimed device.

In view of the foregoing remarks, Applicants submit that the claimed invention, as set forth in claims 6 and 12 as well as independent claim 1, cannot be obvious in view of the teachings of *Schuman* coupled with the knowledge in the art, and this appears to the Office's own hypothesis. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Double Patenting Rejection

Claim 1 has been rejected on the basis of non-statutory obviousness-type double patenting as being unpatentable in view of claims 1 and 3 of U.S. Patent No. 4,944,875.

Without acquiescing to the validity of this rejection and solely in an effort to expedite allowance of the pending claims, Applicants submit that the Applicants will consider filing a

Double Patenting Rejection

Claim 1 has been rejected on the basis of non-statutory obviousness-type double patenting as being unpatentable in view of claims 1 and 3 of U.S. Patent No. 4,944,875.

Without acquiescing to the validity of this rejection and solely in an effort to expedite allowance of the pending claims, Applicants submit that the Applicants will consider filing a terminal disclaimer once the allowance subject matter has been determined, which will obviate this rejection.

Conclusion

In view of the foregoing amendments and arguments, allowance of the instant application with all pending claims is respectfully solicited. If a telephonic conversation with Applicant's attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at the number below. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account no. 13-3577.

Respectfully submitted

Sapna Mehtani, Ph.D., J.D. Attorney for Applicants

Reg. No. 56,126

December 15, 2009 Millipore Corporation 290 Concord Road Billerica, Massachusetts 01821

Tel.: (978) 715-1086 Fax: (978) 715-1382

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on December 15, 2009.